

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Duggan *et al.*

Appl. No.: 09/529,130

35 U.S.C. § 371 Date: June 22, 2000

For: **Conjugates of Galactose-Binding  
Lectins and Clostridial  
Neurotoxins as Analgesics**

Confirmation No.: 2901

Art Unit: 1653

Examiner: Kam, Chih Min

Atty. Docket: 1581.0580000/RWE/ALS

**Fifth Supplemental Information Disclosure Statement**

Commissioner for Patents

PO Box 1450

Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. The numbering on this Fifth Supplemental Information Disclosure Statement is a continuation of the numbering in Applicants' Fourth Supplemental Information Disclosure Statement filed on November 7, 2003 in connection with the above-captioned application.

Further to the recent notice "Changes To Support Implementation of the United States Patent and Trademark Office 21st Century Strategic Plan; Final Rule," copies of all of the U.S. patents or published patent applications cited on the accompanying PTO-1449 forms need not be provided. 1287 O.G. 67 (October 12, 2004); 69 Fed. Reg. 56481 (September 21, 2004).

The Examiner's attention is directed document **AP3** which is the published PCT application from which co-pending U.S. patent application 09/937,484 to Foster *et al.* (35 U.S.C. § 371 date: January 23, 2002) is derived. This U.S. patent application is directed to related technical subject matter. The identification of this U.S. patent application is not to be construed as a waiver of secrecy as to this application now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited application and the art cited therein during examination. Applicants also provide herewith as documents **AT15-AR17** copies of the substantive examination details and Applicants' replies from this co-pending application.

In accordance with 37 C.F.R. § 1.98(a)(3), Applicants' undersigned representative submits the following discussion of the relevance of the non-English language document **AO3** cited on Form PTO 1449: Document **AO3** is in German; an unverified English language translation of document **AO3** is provided as document **AS15**.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection, or Notice of Allowance, or an action that otherwise closes prosecution in the application. Attached is our PTO-2038

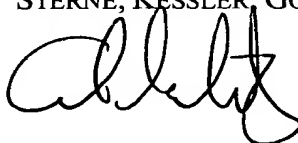
Credit Card Payment Form in the amount of \$180.00 in payment of the fee under 37 C.F.R. § 1.17(p).

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered. This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

Consideration of the cited documents and making the same of record in the prosecution of the above-identified application is respectfully requested. The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

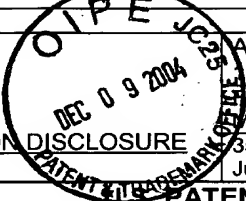
Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

A handwritten signature in black ink, appearing to read 'A. Schwartz', is written over the printed name.

Aaron L. Schwartz  
Agent for Applicants  
Registration No. 48,181

Date: December 9, 2004  
1100 New York Avenue, N.W.  
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(202) 371-2600

FORM PTO-1449				ATTY. DOCKET NO. 1581.0580000/RWE/ALS		APPLICATION NO. 09/529,130	
FIFTH SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT				FIRST NAMED INVENTOR Michael John Duggan		35 U.S.C. § 371 Date June 22, 2000	
				ART UNIT 1653			
<b>U.S. PATENT DOCUMENTS</b>							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA						
	AB						
	AC1	5,433,946	07/18/1995	Allen, Jr. <i>et al.</i>			
	AD1	6,235,313	05/22/2001	Mathiowitz <i>et al.</i>			
	AE						
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<b>FOREIGN PATENT DOCUMENTS</b>							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO3	EP 0 602 686 A2	06/22/1994	Europe			Abstract Yes No
	AP3	WO 00/57897	10/05/2000	WIPO			Yes No
<b>OTHER (Including Author, Title, Date, Pertinent Pages, etc.)</b>							
	AR	<u>10</u>	Diaz, A. and Dickenson, A.H., "Blockade of spinal N- and P-type, but not L-type, calcium channels inhibits the excitability of rat dorsal horn neurones produced by subcutaneous formalin inflammation," <i>Pain</i> 69:93-100, Elsevier Science Ireland Ltd. (January 1997)				
	AS	<u>10</u>	Edmonds, B.T. and Koenig, E., "Transmembrane Cytoskeletal Modulation in Preterminal Growing Axons: I. Arrest of Bulk and Organelle Transport in Goldfish Retinal Ganglion Cell Axons Regenerating In Vitro by Lectins Binding to Sialoglycoconjugates," <i>Cell Motil. Cytoskeleton</i> 17:106-117, Wiley-Liss, Inc. (1990)				
	AT	<u>10</u>	Edmonds, B.T. and Koenig, E., "Transmembrane cytoskeletal modulation in preterminal growing axons. II. <i>Limax flavus</i> agglutinin-induced receptor redistribution, capping and internalization in varicosities of growing axons," <i>J. Neurocytol.</i> 20:232-247, Chapman and Hall Ltd. (1991)				
EXAMINER						DATE CONSIDERED	
<b>EXAMINER:</b> Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.							

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	AL						Yes No
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	AN						Yes No
	AO						Yes No
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**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

	AR	<u>11</u>	Garber, N., <i>et al.</i> , "On the specificity of the D-galactose-binding lectin (PA-I) of <i>Pseudomonas aeruginosa</i> and its strong binding to hydrophobic derivatives of D-galactose and thiogalactose," <i>Biochim. Et Biophys. Acta</i> 1116:331-333, Elsevier Science Publishers B.V. (1992)
	AS	<u>11</u>	Garret, C., <i>et al.</i> , "Pharmacological properties of a potent and selective nonpeptide substance P antagonist," <i>Proc. Natl. Acad. Sci. USA</i> 88:10208-10212, National Academy of Sciences (1991)
	AT	<u>11</u>	Gupta, D., <i>et al.</i> , "Differences in the Cross-Linking Activities of Native and Recombinant <i>Erythrina corallodendron</i> Lectin with Asialofetuin. Evidence for Carbohydrate-Carbohydrate Interactions in Lectin-Glycoprotein Complexes," <i>Biochem.</i> 33:2503-2508, American Chemical Society (1994)

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## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	<u>12</u>	Heilman, R.D., <i>et al.</i> , "An Evaluation of the Hot Plate Technique to Study Narcotic Antagonists," <i>Res. Commun. Chem. Pathol. Pharmacol.</i> 13:635-647, PJD Publications Ltd. (1976)
AS	<u>12</u>	Iglesias, J.L., <i>et al.</i> , "Purification and Properties of a D-Galactose/N-Acetyl-D-galactosamine-Specific Lectin from <i>Erythrina cristagalli</i> ," <i>Eur. J. Biochem.</i> 123:247-252, Blackwell Science Ltd. (1982)
AT	<u>12</u>	Lembeck, F. and Holzer, P., "Substance P as Neurogenic Mediator of Antidromic Vasodilation and Neurogenic Plasma Extravasation," <i>Naunyn-Schmied. Arch. Pharmacol.</i> 310:175-183, Springer-Verlag (1979)

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	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>13</u>	Lis, H. and Sharon, N., "Lectins as Molecules and as Tools," <i>Ann. Rev. Biochem.</i> 55:35-67, Annual Reviews, Inc. (1986)
	AS	<u>13</u>	Pintér, E., <i>et al.</i> , "Lack of evidence for tachykinin NK <sub>1</sub> receptor-mediated neutrophil accumulation in the rat cutaneous microvasculature by thermal injury," <i>Eur. J. Pharmacol.</i> 369:91-98, Elsevier Science B.V. (March 1999)
	AT	<u>13</u>	Silverman, J.D. and Kruger, L., "Selective neuronal glycoconjugate expression in sensory and autonomic ganglia: relation of lectin reactivity to peptide and enzyme markers," <i>J. Neurocytol.</i> 19:789-801, Chapman and Hall Ltd. (1990)

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	AR	<u>14</u>	Sharon, N. and Lis, H., "Legume lectins - a large family of homologous proteins," <i>FASEB J.</i> 4:3198-3208, The Federation of American Societies for Experimental Biology (1990)
	AS	<u>14</u>	Welch, M. and Foster, K., "Chapter 26. Cell Culture of Neurons of the Peripheral Nervous System of Birds and Mammals," in: <i>The Neuron in Tissue Culture</i> , Haynes, L.W., ed., John Wiley & Sons Ltd., New York, N.Y. pp-389-393 (December 1999)
	AT	<u>14</u>	Zambenedetti, P., <i>et al.</i> , "Identification of lectin binding sites in the rat brain," <i>Glycoconj. J.</i> 13:341-346, Chapman & Hall (June 1996)

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	AR	<u>15</u>	Zhou, L., <i>et al.</i> , "Expression and Purification of the Light Chain of Botulinum Neurotoxin A: A Single Mutation Abolishes Its Cleavage of SNAP-25 and Neurotoxicity after Reconstitution with the Heavy Chain," <i>Biochem. 34</i> :15175-15181, American Chemical Society (1995)
	AS	<u>15</u>	Esp@cenet Database 12, English language abstract of European Patent No. 0 602 686 A2 (Document AO3)
	AT	<u>15</u>	Audet, M.A., Office Communication for United States Patent Application No. 09/937,484, 12 pages, United States Patent and Trademark Office (mailed January 29, 2004)

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## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	<u>16</u>	Schwartz, A.L., filing for United States Patent Application No. 09/937,484, 4 pages; "Reply to Restriction Requirement" (filed February 27, 2004)
AS	<u>16</u>	Audet, M.A., Office Communication for United States Patent Application No. 09/937,484, 16 pages, United States Patent and Trademark Office (mailed June 21, 2004)
AT	<u>16</u>	Schwartz, A.L., filing for United States Patent Application No. 09/937,484, 14 pages, "Petition to the Director Under 37 C.F.R. §§ 1.144 and 1.181 to Withdraw Final Restriction Requirement" (filed August 17, 2004)

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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

	AR	<u>17</u>	Schwartz, A.L., filing for United States Patent Application No. 09/937,484, 25 pages with Exhibits A-D, "Amendment and Reply Under 37 C.F.R. § 1.111" (filed September 21, 2004)
	AS		
	AT		

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